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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/874,302

06/05/2001

Robert F. Rioux

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09/11/2006

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EXAMINER

BRANDT, ADAM CURTIS

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/874,302

Applicant(s)

RIOUX, ROBERT F.

Examiner

Adam Brandt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4,6-9,11-18 is/are pending in the application.
- 4a) Of the above claim(s) 3,5 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-9 and 11-18 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

A petition was filed on 1/14/2005 for application number 09/874302 to be withdrawn from issuance. This petition was filed because a foreign associate of the corresponding foreign application number 01941946.4 faxed an office action to the Applicant's attorney. That office action presented art not cited in the U.S. prosecution. In light of the new art, the Applicant's attorney filed the petition and filed a Request for Continued Examination. The petition was granted on 2/09/2006.

#### *Double Patenting*

1. Claims 1, 2, 4, 6, 7-9, 11-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,10-20 of copending Application No.10/973,191. Although the conflicting claims are not identical, they are not patentably distinct from each other because the surgical device disclosed in each application is identical without the addition of any features.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

1. **Claims 1 of US Application No.: 10/973,191 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Application No.: 9/874,302.**

2. **US Application No.: 10/973,191 will be referred as '191 and US Application No.: 9/874,302 will be referred to as '302 from this point forward.**

3. In regards to claim 1 of '191: Claim 1 of '302 recites a surgical instrument for treating female urinary incontinence comprising a handle (part a of claim 1), a shaft extending in a distal direction from the handle and comprising a curved portion, the shaft being adapted to access interior tissue within a human body (part b of claim 1); a blunt tip disposed at a distal end of the shaft for blunt dissection of tissue (part c of claim 1); locating a grasping mechanism at the distal end of a shaft for blunt dissection of tissue (part d of claim 1). Claim 1 of '302 fails to recite a grasping mechanism including a movable element that includes a cutting edge. Claim 11 of '302 teaches that an element can be used to cover a window. Claim 12 of '302 teaches that the element is movable. Claim 13 of '302 teaches that the window and element operate together to grasp a suture or sling. Claim 15 of '302 teaches that the element has a cutting edge. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of claim 1 '302 and the teachings of claims 11, 12, 13, 15 of '302 to have the surgical instrument as disclosed in claim 1 of '191.

4. In regards to claim 10 of '191: Claim 2 of '302 recites a surgical instrument of claim 1, wherein the shaft is adapted to transvaginally access interior tissue within a female human body (claim 2 of '302).

5. In regards to claim 11 of '191: Claim 11 of '302 recites an element for covering the window. Claim 11 of '302 fails to recite the window operated by an actuator, the window being movable between an open position, an intermediate position, and a closed position. Claim 12 of '302 teaches an actuator for operating the element, the element being movable between an open

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position, an intermediate position, and a closed position. It is reasonable to ascertain that since the window is regulated by the movement of the element, that the actuator for operating the element of claim 12 of '302 is essentially operating the window as well. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made combine the element taught in claim 11 of '302 with the actuator and mobility of said element as taught by claim 12 of '302 in order to have the surgical instrument disclosed in claim 11 of '191.

6. In regards to claim 12 of '191: Claim 13 of '302 recites the surgical instrument of claim 11, wherein a suture or a sling maybe introduced into the window when the element is in placed the open position, a suture of a sling may be retained by the window when the element is placed in the intermediate position, and a suture or a sling may be released from the window when the element is placed in the closed position.

7. In regards to claim 13 of '191: Claim 14 of '302 recites the surgical instrument of claim 11, wherein the actuator comprises a knob on the handle.

8. In regards to claim 14 of '191: Claim 6 of '302 recites the surgical instrument of claim 1, wherein the handle comprises a friction based gripping surface.

9. In regards to claim 15 of '191: Claim 7 of '302 reads verbatim on claim 15 of '191

10. In regards to claim 16 of '191: Claim 8 of '302 reads verbatim on claim 16 of '191.

11. In regards to claim 17 of '191: Claim 9 of '302 reads verbatim on claim 17 of '191.
12. In regards to claim 18 of '191: Claim 16 of '302 reads verbatim on claim 18 of '191.
13. In regards to claim 19 of '191: Claim 1 of '302 recites a surgical instrument of claim 1, further comprising an L-shaped slot (part d).
14. In regards to claim 20 of '191: Claim 1 of '302 recites a surgical instrument of claim 1, wherein the L-Shaped slot comprises a longitudinal portion extending longitudinally along a portion of the distal end of the shaft (first leg extending radially inward, claim 1 of '302) and a horizontal portion extending radially into the shaft (second leg extending axially in a distal direction from an inner end of the first leg, claim 1 of '302)

The indicated allowability of claim 1 is withdrawn in view of the newly discovered reference(s) to Skiba et al (US Pub No. US2004/0176802 A1; "Skiba"), Thompson et al. (USPN 5860993;"Thompson"), and Koh et al. (USPN 6254620 B1;"Koh"). Rejections based on the newly cited reference(s) follow.

***Claim Objections***

15. Claim 13 is objected to because of a grammatical error. The Applicant has presented claim 13 to read, "...when the element is in placed the open position...". It is suggested that the Applicant revise claim 13 to read "...when the element is placed in the open position...".

***Claim Rejections - 35 USC § 112***

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Regarding claims 13 and 14, the word "maybe" renders the claim indefinite because it is unclear whether the limitation(s) following the word would actually occur in the use of the instrument.

***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**19. Claims 1, 2, 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skiba in view of Thompson.**

20. In regards to claim 1: Skiba discloses a surgical instrument comprising; a handle (1802); a shaft (1806) extending in a distal direction from the handle and comprising a curved portion (figure 25), the shaft being adapted to access interior within a human body; a tip (1808) disposed at a distal end of the shaft for dissection of tissue; and a window (figure 20) including an L-shaped slot located within a distal end portion of the shaft, the L-shaped slot including a first leg extending radially inward and a second leg extending axially in a distal direction from an inner end of the first leg (figure 20). Skiba fails to disclose that the tip (1808) is blunt. Thompson teaches that a tip is can be smooth and rounded. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Thompson's blunt tip on Skiba's surgical instrument in order to conduct blunt dissection of tissue.

21. In regards to Claim 2: Skiba and Thompson combine to disclose the surgical instrument of claim 1. Additionally, Skiba discloses that the device is useful in laparoscopic surgical procedures (Abstract). Since Skiba's surgical instrument is useful in laparoscopic surgical procedures involve entering the body cavity through a small incision, it is reasonable to say that the Skiba's shaft is adapted to transvaginally access interior tissue within a female human body. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adapt the shaft on the surgical instrument as disclosed by Skiba and Thompson in



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order to access interior tissue within a female body via the vagina for the purposes of suturing or placing an implant.

22. In regards to claim 11: Skiba and Thompson combine to disclose the surgical instrument of claim 1. Additionally, Skiba discloses an element (1904) for covering the window so that suture may be grasped. Therefore, it would have been obvious to one of ordinary skill at the time the invention was made to use the window covering element as described by Skiba in the surgical instrument set forth by Skiba and Thompson in claim 1 in order to hold the suture so that it may be grasped firmly and placed accurately.

23. In regards to claim 12: Skiba and Thompson combine to disclose the surgical instrument of claim 11. Additionally, Skiba discloses an actuator (1804) for operating the element (1904), the element being movable between an open position, an intermediate position, and a closed position (page 3, paragraph 0038). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Skiba's actuator on the surgical instrument of Skiba and Thompson in order to remotely control the position of the element at a point away from the immediate suturing location.

24. In regards to claim 13: Skiba and Thompson combine to disclose the surgical instrument of claim 12. Additionally, Skiba discloses a suture or sling maybe introduced into the window when the element is placed in the open position, a suture or sling may be retained by the window

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when the element is placed in the intermediate position, and a suture or sling may be released from the window when the element is placed in the closed position (page 3, paragraph 0038).

25. Upon close inspection of Skiba (figure 20), the element (1904) is illustrated to translate into several different positions, one of which being a suture locking position. The suture is held in place by applying light friction so that it does not damage the suture (pg 3 paragraph 0039). If the user repeatedly engages the element into the suture locking position, applying light friction, the suture would eventually separate because of cyclical application of frictional force. Therefore, it can be said that Skiba's surgical instrument is capable of may be releasing the suture or sling from the window when the element is placed in the closed position. It is obvious to one of ordinary skill in the art at the time the invention was made to incorporate Skiba's window and element positioning system with the surgical instrument as described previously in claim 12 by Skiba and Thompson so that the surgical instrument can manipulate the suture or sling position variably at the command of the user.

26. In regards to claim 14: Skiba and Thompson combine to disclose the surgical instrument of claim 12. Additionally, Skiba discloses an actuator comprising a knob (1804), located on the handle. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Skiba's knob on the surgical instrument of Skiba and Thompson in order to engage the element actuator at a convenient location relative to a hand gripping the surgical instrument.

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27. In regards to claim 15: Skiba and Thompson combine to disclose the surgical instrument of claim 12. Additionally, Skiba discloses the element comprising a cutting edge (suture engaging edge of 1904).

28. Upon close inspection of Skiba (figure 20), the element (1904) is illustrated to translate into several different positions, one of which being a suture locking position. The suture is held in place by applying light friction so that it does not damage the suture (pg 3 paragraph 0039). If the user repeatedly engages the element into the suture locking position, applying light friction, the suture would eventually separate because of cyclical application of frictional force. Therefore, the edge of the element engaging the suture is capable of cutting the suture thus making it cutting edge. It would have been obvious to one of ordinary skill in the art the time the invention was made to apply a cutting edge to the suture engaging element disclosed by Skiba and Thompson so that a suture can be cut during a surgical procedure.

29. In regards to claim 16: Skiba and Thompson combine to disclose the surgical instrument of claim 15. Additionally, Skiba discloses a suture or sling maybe introduced into the window when the element is placed in the open position, a suture or sling may be retained by the window when the element is placed in the intermediate position, and a suture or sling may be cut by the cutting edge when the element is placed in the closed position (page 3, paragraph 0038).

30. Upon close inspection of Skiba (figure 20), the element (1904) is illustrated to translate into several different positions, one of which being a suture locking position. The suture is held in place by applying light friction so that it does not damage the suture (pg 3 paragraph 0039). If the user repeatedly engages the element into the suture locking position, applying light

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friction, the suture would eventually separate because of cyclical application of frictional force. Therefore, it can be said that Skiba's surgical instrument is capable of may be cutting the suture or sling by the cutting edge when the element is placed in the closed position. It is obvious to one of ordinary skill in the art at the time the invention was made to incorporate Skiba's window and element positioning system with the surgical instrument as described previously in claim 15 by Skiba and Thompson so that the surgical instrument can manipulate the suture or sling position variably at the command of the user.

31. In regards to claim 17: Skiba and Thompson combine to disclose the surgical instrument of claim 1. Additionally, Skiba discloses that the device is useful in laparoscopic surgical procedures (Abstract). Since Skiba's surgical instrument is useful in laparoscopic surgical procedures involve entering the body cavity through a small incision, it is reasonable to say that the Skiba's shaft is adapted for percutaneous access through an incision in the abdominal wall. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adapt the shaft on the surgical instrument as disclosed by Skiba and Thompson in order to perform percutaneous surgical procedures so that sutures can be remotely inserted or cut by the surgical instrument.

32. In regards to claim 18: Skiba and Thompson combine to disclose the surgical instrument of claim 1. Additionally, Skiba discloses that the device is useful in laparoscopic surgical procedures (Abstract). Since Skiba's surgical instrument is useful in laparoscopic surgical procedures involve entering the body cavity through a small incision, it is reasonable to say that

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the Skiba's shaft is adapted to place an implant introduced through a vaginal incision. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adapt the shaft on the surgical instrument as disclosed by Skiba and Thompson in order to place implants through an incision in the vagina for the purposes of releasing or grasping the implant remotely.

**33. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Skiba in view of Thompson and Koh et al. (USPN 6254620 B1;"Koh").**

34. Skiba and Thompson combine to disclose the surgical instrument of claim 1. Skiba and Thompson fail to disclose a surgical instrument wherein the handle comprises a friction based gripping surface. Koh illustrates that it well known in the art to implement an increased frictional arrangement on the surface of a handle (12). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to combine the surgical instrument of Skiba and Thompson with the friction based gripping surface of Koh in order to prevent hand of the user slipping when being employed.

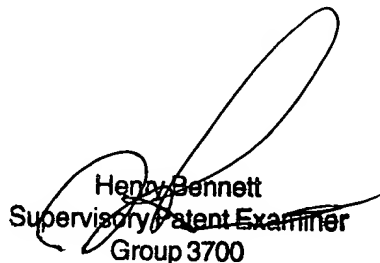
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Brandt whose telephone number is 571-272-7199. The examiner can normally be reached on 8:30 AM to 4:30 PM; Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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